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(54) TREATMENT DEVICE FOR WOUNDS

(71) I, HERBERT S. LOSEFF, a citizen of the United States of America, of Winnetka, County of Cook, State of Illinois, United States of America, do hereby declare

the invention, for which I pray that a patent may be granted to me, and the method by which it is to be performed, to be particularly described in and by the following statement:—

This invention relates to devices for treatment of a wound, more particularly, flushing or drainage devices. As used herein, the term wound is used to encompass areas of treatment other than injury, such as body cavities, abscesses, and other sites where excesses of body fluids or bacteria may accumulate.

When a patient has a serious, deep wound, or a large abscess, osteomyelitis, or other collections of body fluids such as serum, blood, or pus in the body, drainage catheter tubing is commonly used to alleviate the situation. Commonly, the drainage tubing is made of flexible plastic such as polyethylene, or inert elastomers such as silicone rubber or the like. Typically, the drainage tubing is fabricated to have sufficient stiffness so that fluids can be removed through it by suction without collapsing the tubing, for example, by an evacuator such as is shown in U.S. Patent No. 3,115,138.

The drainage tubing typically is manufactured with a large number of lateral perforations for communication between the lumen or bore of the tubing and the exterior, the perforations being located in a central portion of the tubing, the ends of the tubing being free of lateral perforations.

For emplacement in the wound site, a pointed steel awl is connected to one end of the tubing, to draw the tubing through healthy, intact tissue adjacent the wound in such a manner that at least one end of the tubing is positioned exterior of the patient, while the perforated portion lies at the wound site. Following this, excess portions of the tubing, and the awl, are removed, for example by severing the tubing, and the wound site is sutured.

Various significant problems arise from the use of known drainage tubing. First, the restless patient can accidentally, or otherwise, pull on the tubing and cause it to withdraw outwardly along its path through the healthy tissue. This can happen inadvertently when the patient is asleep, or irrational patients and children may intentionally try to withdraw the tubing.

Once the tubing has been partially or completely withdrawn, those portions of the tubing which have been exposed to the exterior will become contaminated with bacteria, and thus should not be simply reinserted into the patient again, even if this were possible. Accordingly, a fresh tubing may have to be reinserted by again punching it (with an awl) through healthy tissue into the wound site. Also, the stitches holding the wound closed may well have to be re-opened in order to withdraw the awl and to re-position the fresh tubing.

Furthermore, at the skin exit hole or holes for the tubing, there is a pronounced tendency for blood, lymph, or irrigation solution to leak outwardly, which is clearly undesirable. There is the still more undesirable possibility of the migration of bacterial contamination inwardly toward the wound site along the tubing, and the consequent danger of infection.

Also, the perforations and the bore or lumen of the tubing at the wound site frequently become plugged with debris. To avoid changing of the tubing, there is frequently attempted a back flushing procedure, in which sterile flushing solution, such as normal saline, is passed through the tubing to flush the solution into the wound site. This disperses and breaks up the debris which blocks flow in the tubing. This technique has its consequent dangers of introducing bacterial contamination from the exterior into the wound site. The problems present with tubing will be recognised by one skilled as being present in tubing lodged in any body cavity, such as in the abdomen, chest, head, neck, or limbs.

In accordance with the present invention, a device for treatment of a wound comprises a tubular member having a central lumen and ports in the wall along a portion

thereof; an elastomeric retention balloon carried by the tubular member spaced along the tubular member from said portion, and tubular means extending from the retention balloon for inflation thereof; a squeeze bulb for connection to the end of the tubular member further spaced in the same direction along the tubular member from said portion thereof than the retention balloon; and means for selectively attaching an awl to either end of the tubular member whereby the tubular member may be drawn into an operative position with respect to a wound in either direction through adjacent tissue.

In a modification of a device according to the invention, the squeeze bulb is permanently connected to said end of the tubular member, said selectively attaching means being provided only for attaching a said awl to the other end thereof.

The tubular means for inflating the retention balloon is normally provided along a length of the tubular member extending away from the ported portion and sealed along its length. Preferably it is of a piercable but resealable material enabling it to be pierced by for example, a hypodermic needle to permit pumping in a sufficient amount of air to inflate the retention balloon, after which withdrawal of the needle permits the fine hole left thereby to be sealed by the elastomeric character of the material. In use, the balloon is usually positioned to be inflatable under sound tissue, such as under the skin of a patient, while the drainage ports lie in the wound or cavity site.

It is preferred that the ported portion of the tubular member is located between the retention balloon and an imperforate end length of the tubular member to facilitate connection of the tubular member with an awl, for installation of the device in a manner described below, as well as to provide flexibility of use.

The squeeze bulb can be used as a storage container for retention of a flushing solution outside the body when the drainage device is positioned in a patient with the drainage ports located in the wound or body cavity site. With the squeeze bulb connected, the central lumen of the tubular member can be sealed from the exterior by appropriate clamp means after filling with flushing solution, and the squeeze bulb can be squeezed and manipulated for aseptic back flushing of the device, while the tubular member is sealed against possible bacterial contamination from the outside. Thus, the wound site can be bathed or back-flushed with any desired solution in a manner which reduces the risk of contaminating the wound site. In preferred embodiments of the invention the tubular means for the retention balloon terminates adjacent to but short of the squeeze bulb or connection therefor whether the squeeze bulb is integral with or attachable to the tubular member.

The ports in the tubular member will normally be of smaller aperture size than the diameter of the central lumen of the tubular member. As a result of this, the drainage ports serve to screen out matter such as tissue particles and small blood clots, preventing them from entering the central lumen and causing obstruction within the tubular member.

It is generally desirable for the tubular member and retention balloon of the device to be made of silicone rubber, since such material is highly non-adherent to clots and debris, and is thus easily flushed. Also very little tissue reaction occurs in tissue which is in prolonged contact with silicone rubber resulting in greater comfort for the patient than with other materials. If desired, other materials such as organic plastics or rubber may be used, but it is preferred that such materials are fabricated with a coating of room-temperature-vulcanizing silicone rubber for essentially equivalent effect.

Other hydrophobic, flexible thermoplastic materials, such as polyethylene, can also be used with advantage to fabricate devices of the invention. Other corresponding medical grade materials such as latex rubber and polyvynylchloride plastisol can also be used.

In normal use, the tubular member is inserted into the wound site in such a position that the lateral drainage ports are in flow communication with the wound site. The tubular member is passed through healthy, intact tissue adjacent the wound site so that one end of the tubular member is exposed to and communicates with the exterior of the patient, and in such manner that the retention balloon is positioned within the healthy, intact tissue adjacent the skin. Generally, either of the above steps may be performed first with equivalent effect.

After the tubular member has been properly emplaced, the retention balloon is inflated, to firmly retain the drainage member in the wound site, so that it is less likely to be accidentally or otherwise removed from proper emplacement by pulling on an exposed portion of the tubular member. Likewise, the pressurized retention balloon provides an improved seal at and just below the skin level, which greatly reduces or eliminates bleeding and fluid leakage from the skin hole through which the tubular member passes. The retention balloon also reduces the possibility that bacterial contamination can enter the skin hole to cause infection.

Devices according to the invention will now be described by way of example and

with reference to the accompanying drawings wherein:

Figure 1 is an illustrative view, with some portions broken away, showing the use of one embodiment of the invention, and illustrating the emplacement of the tubing by drawing it into the wound from without the wound; and

Figure 2 is a fragmentary view, showing another embodiment of the invention wherein the tubing may be emplaced by being drawn into position from within the wound, after which a squeeze bulb may be connected thereto, the device thereafter operating in the same manner as that of Figure 1.

Referring to the drawings, Figure 1 shows a device 10 which comprises a tubular member 11 of flexible, plastics tubing such as silicone rubber, polyethylene, or medical grade polyvinyl chloride plastisol, which is typically two or three feet in length. The tubing has a central lumen 12 which may be about $\frac{1}{8}$ inch in diameter or other diameters as required. The device has a lead in end 18 and the other end is at 20.

A first, intermediate portion 16 of tubular member 11 defines a plurality of lateral drainage ports 17 in the wall of the member for fluid communication between lumen 12 and the exterior of tubular member 11. The portion 16 of the tubular member is spaced from the end 18 thereof, by a length of normally at least 3 inches, and preferably 6 to 8 inches, of port-free tubing for purposes which will become apparent below.

A retention balloon 22 is positioned on the tubular member spaced from drainage ports 17. Balloon 22 is generally positioned so that it can be inflated under the skin of a patient when the drainage ports lie in a wound site. Balloon 22 may be fabricated in a conventional manner by appropriately gluing or otherwise sealing an elastomeric sleeve at regions 24 and 25 to the tubing 11. The material of the balloon 22 has an extension 26 sealed along its length to the exterior wall of the tube 11 and defining either within itself or with the exterior of tube 11 a sealed passageway 27 for inflating the balloon 22. The balloon 22 may be inflated by passing for example saline solution or air through the passageway 27. The passageway 27 is of relatively small dimension and does not appreciably enlarge the total diameter of the combined tube 11 and passageway 27. The end 28 of extension 26 is sealed to tube 11, but is pierceable, as is well known in the art, by a hypodermic needle 30 for pumping air or liquid through the passageway 27 to inflate the balloon 22. Balloon 22 is preferably made of an elastomer such as silicone rubber, or alternatively, natural latex.

A portion of tubing 11 beyond the end 28 of passageway 27 and spaced therefrom forms a squeeze bulb 32, which may be used as a storage portion for retention of a flushing solution (such as physiological saline, containing an antibiotic) in a position outside of the body when the tubular member is positioned in a patient. The end portion 20 of the member may be sealed by a conventional screw clamp 34, or the like that slips over the end 20, so that the central lumen 12 and the squeeze bulb 32 may be filled with a flushing solution, and then the clamp 34 may be closed to seal same from communication with the exterior.

As shown in Figure 1, a conventional awl 36 having a threaded connector member 38, of appropriate size, is threaded into end 18 of the tubular member. The member can then be emplaced in an open wound 40 on the body 42 of a patient. The surgeon penetrates the skin, or tissue, at a point 44 spaced from the wound 40, to pass the awl through intact, healthy tissue, manipulating the awl so that it enters the wound site at a point 46. Tubular member 11 can then be drawn through the punctured path 48 through the intact, healthy tissue until the portion 16 of the tubing defining the drainage ports 17 lies in the wound site and retention balloon 22 has entered skin opening 44. Some surgeons may prefer to allow a portion of balloon member 22 to remain outside of skin opening 44. Also, for best sealing, it is generally preferable for retention balloon 22 to be in contact with skin opening 44 and not to be significantly spaced therefrom.

Following this, section 16 of the tubing is positioned as desired by the surgeon in the wound 40, and tubular member severed at a location indicated generally at 49, in accordance with the discretion of the surgeon, so that the awl 36 and usually most of the port-free end portion 18 of the tubing can be removed. Accordingly, the portion 16 is positioned, without the need to handle or touch it, since manipulations of the tubing for mounting and using the awl 36 can be confined to imperforate end 18 of the tubing. Accordingly, portion 16 of the member 11 can more likely remain in asceptic condition. The wound 40 may then be sutured, with the drainage port-defining portion 16 remaining positioned within the wound site.

At the discretion of the surgeon, when he believes the wound tubing to be satisfactorily positioned, balloon 22 can be inflated, typically by pumping in through the passageway 27 physiological saline solution, gas or air by means of a hypodermic needle 28 to which may be connected a conventional syringe or pump, to inflate balloon 22 to the degree desired, and thus provide firm anchoring of the tubular member 11 coupled with sealing of puncture site 44 in the skin.

The squeeze bulb 32 can be collapsed, generally by hand, to force flushing solution through drainage ports 17, as well as the severed end of tubing 11 within wound site 40, to flush the tubular member in an aseptic manner as desired by the physician.

If the wound site is not open to the exterior, then the surgeon must use the awl to define another exit path through intact tissue in order to position the tubular member properly. In this event, both ends of the tubular member protrude from the patient, and can be used for drainage and flushing, but the retention and sealing of one end is still provided by balloon 22. For such special use, a second balloon could be provided for sealing and retaining the second end of the tubular member.

The clamp 34 can be opened to replace the flushing solution, or to subject the wound site to an alternating suction-irrigation treatment with antibiotics and other medicinals, for bathing the wound continuously with therapeutic agents.

Figure 2 shows another, preferred embodiment of the invention, which comprises a similar tubular drainage member 11*a* which has a plurality of drainage ports 17*a* through a first portion 16*a* thereof, the portion 16*a* being spaced from the ends thereof in a manner similar to the embodiment of Figure 1. A similar retention balloon 22*a* is also provided, with an inflation passageway 27*a*. In this form the extension 26*a* that seals to the outer wall of tubular member 11*a* to define the passageway 27*a* is shown separate from but sealed to the retention balloon 22*a* and providing a pierceable end wall 28*a*. It is contemplated that adjacent ducts having a common wall therebetween might be formed by extrusion to form member 11*a* and passageway 27*a* and then sealed where desirable to provide a confined passageway that communicates only with balloon 22. The material of the wall of passageway 27*a* is collapsible under laterial pressure, and the cross-section thereof is small relative to the cross-section of tubular member 11*a*.

In this embodiment, a tubular element 50, which is separate from tubular member 11*a* is provided. Element 50 has a collapsable lumen of larger diameter than member 11*a* to form a squeeze bulb 52, and a connector 54 for connection in aseptic, leakproof manner with an end 19 of the member 11*a* when desired. The squeeze bulb 52 has a nipple end 20*a* that may slidably receive a clamp 34*a*. Connector 54 may be a hollow tubular member with threads on the outside proportioned to screw into the lumen of member 11*a* for connection therewith. Connector 54 may also be a simple nipple or luer connector for liquid-tight fit into the central lumen of member 11*a*.

An advantage of the embodiment of Figure 2 is that it may be either emplaced in a wound 40 in the manner described above with respect to Figure 1, or may be emplaced in the wound in reverse manner. An awl may be emplaced in the bore of the end 19 of member 11*a*, so that the awl may enter the intact, healthy tissue at point 46 (Figure 1) and pass through the tissue until it exits at point 44, should the surgeon find it desirable to do so. The relatively small cross-sectional size of the additional passageway 27*a* compared to the cross-section of the tubular member 11*a*, and its collapsible nature readily permits such an operation. Member 11*a* can then be positioned in a manner comparable to that shown in Figure 1 and the awl may be removed. Then, tubular element 50 may, if desired, be aseptically connected to end 19, and the device used in the manner previously described. The lengths of tubular member 11*a* extending beyond the passageway 27*a* and the perforate portion 16*a* permit selective connection of an awl to one or the other, as desired, without contaminating the drainage ports or damaging the retention balloon.

If desired, either device illustrated may be connected at its respective end 20 or 20*a* to a parenteral solution container to provide a supply of pressurized flushing solution as desired. Clamp 34, 34*a* can be used to control the access of such solution to the respective member 11, 11*a*.

When it is determined that the tubular member should be removed from a wound, balloon 22, 22*a* may be deflated through withdrawal of the inflating gas or fluid by use of a hypodermic or merely by rupturing the wall of passageway 27, 27*a*. Member 11, 11*a* can then simply be withdrawn through skin hole 44 without opening of the stitches of wound 40.

While in the preferred use of the device of the invention, the retention balloon 22 is positioned to be inflatable in the patient's flesh just under the skin, if the doctor feels that it is desirable or advisable, the balloon may be located anywhere along the length of the puncture path 48 made by the awl, or even within the wound itself, and be inflated therein.

It is contemplated that two (or more) devices of this invention may be simultaneously emplaced in a wound site. One of the devices may be used as a flushing fluid inlet, while the other drainage device serves as an outlet for the fluid and other drainage.

WHAT I CLAIM IS:—

1. A device for treatment of a wound comprising a tubular member having a central lumen and ports in the wall along a portion thereof; an elastomeric retention balloon carried by the tubular member and

spaced along the tubular member from said portion, and tubular means extending from the retention balloon for inflation thereof; a squeeze bulb for connection to the end of the tubular member further spaced in the same direction along the tubular member from said portion thereof than the retention balloon; and means for selectively attaching an awl to either end of the tubular member whereby the tubular member may be drawn into an operative position with respect to a wound in either direction through adjacent tissue.

2. A device according to Claim 1 wherein the ports are smaller in size than the cross-section of the central lumen of the tubular member.

3. A device according to Claim 1 or Claim 2 wherein the tubular member and retention balloon each comprise silicon rubber.

4. A device according to any preceding claim wherein the tubular means extends adjacent the tubular member.

5. A device according to Claim 4 wherein the tubular means comprises a sealed passageway, the wall of which is integral with that of the tubular member.

6. A device according to any preceding claim wherein the tubular means is of pierceable but self-sealing material capable of maintaining fluid pressure in the retention balloon.

7. A device according to any preceding claim wherein said portion of the tubular member is located between the retention balloon and an imperforate end length of the tubular member.

8. A device according to Claim 7 wherein the length of said end length is at least three inches.

9. A device according to any preceding claim wherein the squeeze bulb is formed with a passageway extending therefrom, the device including means for selectively closing said passageway.

10. A modification of a device according to any preceding claim wherein the squeeze bulb is permanently connected to said end of the tubular member, said selectively attaching means being provided only for attaching a said awl to the other end thereof.

11. A device for treatment of a wound substantially as herein illustrated by Figure 1 of the accompanying drawings.

12. A device for treatment of a wound substantially as described herein with reference to and as illustrated by Figure 2 of the accompanying drawings.

For the Applicant:
LLOYD, WISE, BOULY & HAIG,
Chartered Patent Agents,
Norman House, 105—109 Strand,
London WC2R 0AE.

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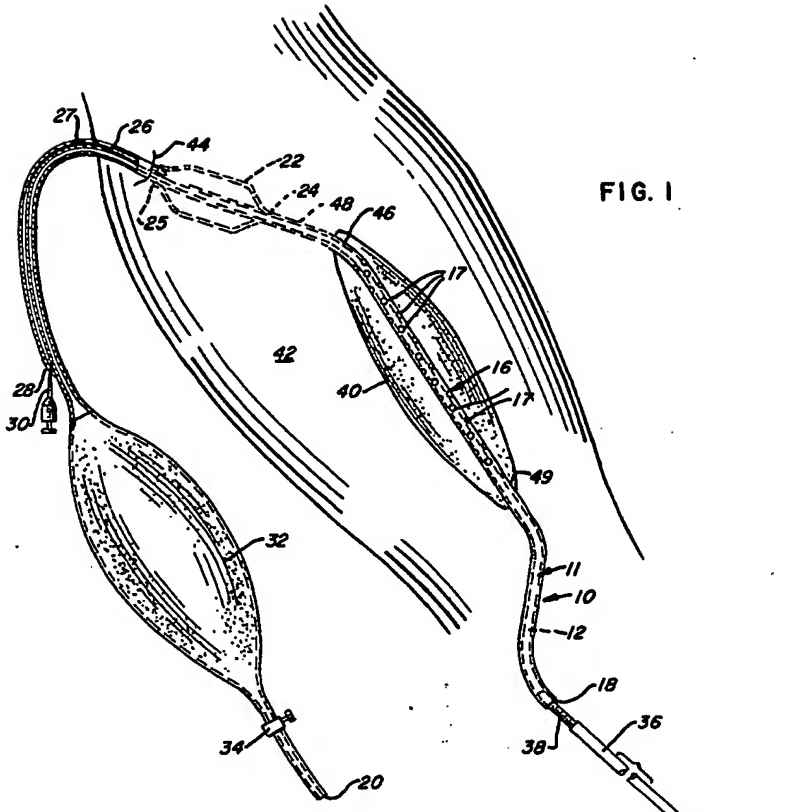

FIG. 1

FIG. 2